**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF ILLINOIS**

| | | |
|---|---|---|
| **IN RE: YASMIN AND YAZ (DROSPIRENONE) MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION** | ) | **3:09-md-02100-DRH-PMF** |
| | ) | **MDL No. 2100** |

**This Document Relates to:**

*Kaitlyn Dietrick v.* No. 3:10-cv-12310-DRH-PMF
*Bayer HealthCare Pharmaceuticals, Inc., et al.*

**BAYER'S OPPOSITION TO THE PSC'S MOTION FOR AUTHORITY TO PUBLICIZE CONFIDENTIAL DOCUMENTS IN CONNECTION WITH PETITION TO THE FDA AND ITS ADVISORY COMMITTEE**

Bayer does not contest plaintiff's right to petition her government. Nor does Bayer contest plaintiff's right to submit a brief to the FDA and its Advisory Committee setting forth her views regarding the safety of Yasmin® and YAZ®. What Bayer objects to is the PSC's invocation of a supposed First Amendment "right" to use confidential documents obtained through discovery to end-run:

> (1) The Protective Order to which the PSC agreed (D.E. 291 in MDL 09-2100); and
>
> (2) This Court's September 14, 2011 Order instructing the PSC that Bayer's supplemental production of "advisory committee materials and/or custodial file materials" were to be treated as confidential and "shall not be used by plaintiffs to interfere with or influence the outcome of any pending advisory committee hearings" (D.E. 1977 in MDL 09-2100).[1]

As demonstrated below, plaintiff's First Amendment rights are not at issue. The Supreme Court has unambiguously held that a protective order issued with "good cause" to restrict dissemination of discovery materials does not offend the First Amendment. *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 37 (1984). And this Court has found that protection of trade secrets,

[1] Instead of challenging documents from those supplemental productions, the PSC seeks to use documents produced by Bayer earlier in the litigation.

intellectual property, and personal data protected under Germany privacy law constitutes good cause for a protective order.

The only question properly before this Court is whether the documents the PSC has challenged were properly designated as confidential under the Protective Order. All 49[2] documents were properly designated as confidential under the terms of the Protective Order and plaintiffs are therefore barred from using those documents for any purpose other than prosecuting this litigation. The PSC's motion should be denied.[3]

## BACKGROUND

One of the first orders of business in this MDL was entry of a Protective Order to guard the confidentiality of certain documents produced in discovery. That Order – stipulated by the parties and entered within a month of the first status conference – provides that "[d]isclosure and discovery activity in this proceeding…may involve production of confidential, proprietary, and private information **for which special protection from public disclosure and *from use for any purpose other than prosecuting this litigation* would be warranted**." CMO 7 (D.E. 291 in MDL 09-2100) at § I.A (emphasis added). The Protective Order does not provide blanket protection of documents produced in this litigation. Instead, it allows a producing party to designate as confidential "information that…constitutes, reflects, discloses, or contains

[2] The PSC has asked the Court for permission to make public 58 documents produced by Bayer in connection with this litigation. Bayer agrees to de-designate eight of those documents. *See* Bayer Addendum Items 8, 10, 12, 31, 44, 48, 52, and 55 (filed under seal). Bayer also agrees to de-designate Bayer Addendum Item 14, which discusses re-analysis data from plaintiffs' expert, Dr. Lidegaard, to the extent the PSC confirms with Dr. Lidegaard that he has no reservations about making public the data discussed in that document on the grounds that it has not yet been published, including in his recent BMJ article. Another document, Bayer Addendum Item 54, was never designated by Bayer as confidential. Bayer's counsel informed the PSC of this fact on October 21, 2011. As a result, 48 documents are at issue.

[3] For ease of reference, Bayer has submitted under seal with this brief its own addendum describing the documents at issue ("Bayer Addendum"). This addendum adopts the numbering used in the PSC's Sealed Addendum to D.E. 2051 in MDL 09-2100.

information subject to protection under Fed. R. Civ. P. 26(c) or other applicable law." *Id*. at § II.D.

The Protective Order also explicitly provides that "[a]ny entity organized under the laws of Germany that becomes a party to this litigation may designate as CONFIDENTIAL those documents…containing 'personal data' within the meaning of the German Federal Data Protection Act, the confidentiality of which is protected under German law." *Id*. at § II.B. When plaintiff Cathy Walton moved to vacate the Order just ten days after its entry, arguing that she had not agreed "to be bound to any protective order in this case, much less one that apparently applies German law in whole or in part," (D.E. 14 in 09-cv-10217 at 2), this Court denied Ms. Walton's motion, holding that the Protective Order would "facilitate the discovery of relevant information and expedite the discovery process by allowing the parties to conduct discovery in a coordinated and efficient fashion, as well as conserving judicial resources." (D.E. 377 in MDL 09-2100).

The Protective Order has allowed the Bayer Defendants to efficiently produce more than 90 million pages of documents during discovery, including more than 22 million pages of documents from Bayer Pharma AG, which is subject to restrictions on the dissemination of personal data imposed by the German Federal Data Protection Act ("BDSG").

In August 2011, the PSC challenged the applicability of German privacy laws to the EURAS Case Summaries. *See Plaintiffs' Memorandum in Opposition to Defendants' Motion to Maintain Confidentiality Designation of EURAS Case Summaries* (D.E. 1936 in MDL 09-2100). In doing so, plaintiffs acknowledged that Bayer Pharma AG may properly designate as confidential materials subject to the BDSG, *id*. at 5, and challenged only whether the Case Summaries were properly designated as confidential under that law, *id*. at 6-10. The Court

upheld the confidentiality of the Case Summaries, confirming the general applicability of German privacy laws to documents produced by Bayer Pharma AG and holding that "Plaintiffs have failed to convince this court that the confidentiality designation can be removed…without directly violating German law…." (D.E. 1971 in MDL 09-2100).[4]

The PSC's present motion, through plaintiff Kaitlin Dietrick, is, in fact, a full-out attack on the Protective Order to which plaintiffs previously agreed. *See generally* D.E. 2051 ("Pl. Mot.") and D.E. 2068 ("Pl. Supp. Br.") (MDL 09-2100). Though the PSC makes some attempt to argue that the documents at issue were not properly designated as confidential, the thrust of their argument is that Ms. Dietrick has a First Amendment right to use confidential documents in a public filing and that this purported right trumps any confidentiality designations. *See*, *e.g.* Pl. Mot. at 5 ("Whatever protections these Defendants, including the foreign Defendants, claim under the laws of the United States, those protections can not undermine the right provided to Ms. Dietrick 220 years ago in the First Amendment to our Constitution"); Pl. Supp. Br. at 16 ("Although a number of the documents at issue originated in Germany, an overriding interest exists for the application of U.S. law"). The PSC's position, if accepted, would render protective orders like the one agreed to and entered in this litigation meaningless, as it would allow plaintiffs to agree to application of certain principles of confidentiality for the purpose of obtaining documents in discovery, and to then turn their backs on such agreements once they have obtained possession of the documents, arguing that the very principles to which they agreed are trumped by the First Amendment.

[4] The PSC included the EURAS case summaries in their October 7, 2011 confidentiality challenge. Bayer informed plaintiffs that the document must remain confidential pursuant to the BDSG and pointed them to this Court's order on that issue. The PSC did not include the EURAS case summaries as a document at issue in the motion to which Bayer now responds, but challenged the confidentiality of those summaries, for a third time, on October 25, 2011.

## ARGUMENT

### I. PLAINTIFF HAS NO FIRST AMENDMENT RIGHT TO DISSEMINATE CONFIDENTIAL MATERIALS OBTAINED THROUGH PRETRIAL DISCOVERY.

The PSC presents this Court with a false choice: either de-designate certain documents that Bayer has designated as confidential or preclude plaintiff from petitioning the government at the upcoming FDA Advisory Committee meeting. *See* Pl. Mot. at 7 ("Plaintiff must substantially abandon this liberty because the defendants refuse to permit the disclosure of certain information"); Pl. Supp. Br. at 16 ("[A] fundamental right to petition her government…will be critically impaired if she is not permitted to use the subject information"). That is not true. Plaintiff is free to petition FDA and may support her petition with any non-confidential information obtained through discovery, or any information gathered outside the discovery process. *See Seattle Times*, 467 U.S. at 33 ("[T]he party may disseminate the identical information…gained through means independent of the court's processes"). "The right to petition the government for grievances is not unlimited." *Wagner v. City of Holyoke*, 241 F. Supp. 2d 78, 103 (D. Mass. 2003) (Ponsor, J.). That plaintiff is restricted from petitioning FDA with *confidential* materials acquired from Bayer for use in this litigation does not constitute a First Amendment violation. The fact that certain documents have been designated as confidential to avoid a conflict with German law does not endow plaintiff with a First Amendment right where none exists.

#### A. Protective Orders Limiting the Dissemination of Discovery Materials Under Federal Rule of Civil Procedure 26(c) Do Not Violate a Party's First Amendment Rights.

The PSC argues that Bayer's right to have confidential documents protected during pretrial discovery must "not obstruct [plaintiff's] First Amendment right" and "yield to the Right to Petition." Pl. Mot. at 2. The PSC's position has been squarely rejected by the United States

Supreme Court. *Seattle Times*, 467 U.S. at 31 (a litigant does not necessarily have "an unrestrained First Amendment right to disseminate information that has been obtained through pretrial discovery"). In *Seattle Times*, the Supreme Court denied a First Amendment challenge to a state court protective order that prohibited plaintiffs from publishing, disseminating, or using certain information obtained through discovery except in ways necessary to prepare for and try their case. *Id*. at 20. The Supreme Court held that a protective order limiting the dissemination of discovery materials does not offend the First Amendment where it (i) is entered on a showing of good cause, (ii) is limited to the context of pretrial discovery, and (iii) does not restrict the dissemination of information gained from outside the discovery process. *Id*. at 37. "A litigant has no First Amendment right of access to information made available only for purposes of trying his suit.…Thus, continued court control over the discovered information does not raise the same specter of government censorship that such control might suggest in other situations." *Id*. at 32.

Since *Seattle Times*, courts have consistently stated that, upon issuance of a valid protective order under Federal Rule of Civil Procedure 26(c), a litigant has no First Amendment right to disclose confidential information obtained through pretrial discovery. *See, e.g., Reyes v. Freeberry*, 141 Fed. Appx. 49, 51 (3d Cir. 2005) ("When a civil litigant obtains discovery pursuant to a valid protective order, the litigant has no First Amendment right to disclose the information"); *U.S. v. Microsoft Corp*., 165 F.3d 952, 959-60 (D.C.C. 1999) ("[T]he good cause standard of Rule 26(c) comports with the first amendment not fortuitously but precisely because it takes into account all relevant interests, including those protected by the first amendment"); *Cipollone v. Liggett Group, Inc*., 785 F.2d 1108, 1119 (3d Cir. 1986) (concluding that "*Seattle Times* prohibits a court considering a protective order from concerning itself with first

amendment considerations"); *Jackson v. U.S.*, No. 3:09-cv-26-J-34, 2009 WL 2436577, at *3 (M.D. Fla. Aug. 6, 2009) (Morris, M.J.) ("[A] party, or non-party, to a law suit possess no First Amendment rights to information that has been protected pursuant to the provisions of Fed.R.Civ.P. 26(c)").

Therefore, courts reject First Amendment challenges to protective orders—like the challenge advanced by the PSC here—where a party demonstrates "good cause" to restrict access to or dissemination of materials obtained through discovery. *See In re Zyprexa Injunction*, 474 F. Supp. 2d 385, 423 (E.D.N.Y. 2007) (Weinstein, J.) (protective order restricting dissemination of confidential materials produced in discovery did not violate parties' First Amendment rights); *In re Alexander Grant & Co. Litig.*, 820 F.2d 352, 355 (11th Cir. 1987) (First Amendment did not entitle publisher and journalist to access confidential materials produced in discovery where protective order was issued upon good cause); *Pamlab, L.L.C. v. Brookstone Pharms., L.L.C.*, No. 09-7434, 2010 WL 4363870, at *4 (E.D. La. Oct. 22, 2010) (Knowles, III, M.J.) (rejecting plaintiff's request to remove confidential designation from defendant's discovery responses in reliance on *Seattle Times*).[5]

[5] In an October 28, 2011 e-mail to the court, the PSC characterized *Seattle Times* as "inapposite" because it involved a litigant's attempt to publicize confidential information in a newspaper, as opposed to an FDA hearing. October 28, 2011 E-mail from P. Pennock ("Oct. 28 E-mail") (Ex. A). There is no support for the PSC's assertion that *where* a plaintiff seeks to publicize confidential information received during pretrial discovery dictates her right to do so. The PSC also sought to distinguish *Seattle Times* by citing a footnote that states that litigants do not surrender their First Amendment rights at the courthouse door. *See* Oct. 28 E-mail (citing *Seattle Times*, 467 U.S. at 32, n.18). In fact, the Supreme Court stated that "***although*** litigants do not surrender their First Amendment rights at the courthouse door…***those rights may be subordinated*** to other interests that arise in this setting," *Seattle Times*, 467 U.S. at 32, n.18 (internal quotation marks omitted; emphasis added), *i.e.*, the government's interest in ensuring that confidential information received only for discovery purposes not be used for purposes outside of litigation. *See id.* at 35 ("There is an opportunity, therefore, for litigants to obtain—incidentally or purposefully—information that not only is irrelevant but if publicly released

Not surprisingly, the PSC does not identify or distinguish the case law uniformly rejecting its position. Nor does the PSC cite a single case that grants the relief it requests on First Amendment grounds. Rather, the PSC seeks to bolster its argument with cases that *generally* speak of an individual's right to petition the government, *see*, *e.g.*, Pl. Mot. at 6 (citing *Borough of Duryea, Pa. v. Guarnieri*, 131 S. Ct. 2488, 2495 (2011)), or present scenarios inapplicable to this case, *see*, *e.g.*, *id.* at 8 (citing *Jepson, Inc. v. Makita Electric Works, Ltd.*, 30 F.3d 854, 858 (7th Cir. 1994) ("***Absent a protective order***, parties to a law suit may disseminate materials obtained during discovery")) (emphasis added).[6]

In addition, the PSC asks this Court to ignore Supreme Court precedent and apply a "high level of scrutiny" to Bayer's confidential designations, on the grounds that the designations impose an impermissible "prior restraint" on the exercise of plaintiff's First Amendment rights. Pl. Supp. Br. at 5-6. This is an argument rejected by *Seattle Times* and its progeny. *Seattle Times*, 467 U.S. at 33 ("[A]n order prohibiting dissemination of discovered information before trial ***is not the kind of classic prior restraint that requires exacting First Amendment scrutiny***") (emphasis added); *accord U.S. v. Caparros*, 800 F.2d 23, 25 (2d Cir. 1986) (rejecting defendant's "contention that the protective order here is an impermissible prior restraint" as "inconsistent" with *Seattle Times*); *In re Alexander Grant & Co Litig.*, 629 F. Supp. 593, 594 (S.D. Fla. 1986) (Gonzalez, J.) (protective order setting guidelines for designation of specific matters and proceedings as confidential did not operate as "prior restraint" on dissemination of

---

could be damaging to reputation and privacy. The government clearly has a substantial interest in preventing this sort of abuse of its processes.").

[6] The PSC also argues that plaintiff's First Amendment right to petition is "buttressed" by the Administrative Procedure Act and FDA regulations. Pl. Mot. at 6-7. Neither source, however, either explicitly or implicitly states that inherent in an individual's right to petition FDA is the right to disseminate confidential materials obtained through pretrial discovery.

information in the public domain). None of the case law cited by the PSC holds otherwise.[7] In fact, one of the "prior restraint" cases the PSC cites, *Procter & Gamble,* explicitly distinguished the issue before it—prohibition against publication of a news story - from the issue before this Court—dissemination of information gained through discovery by a litigant. 78 F.3d at 225.

The PSC also may not justify the relief it seeks by asserting the need to raise public awareness of the issues in this litigation. *See* Pl. Mot. at 6 (claiming that her "motivation in bringing her claims was to raise awareness surrounding this important safety issue" and the FDA Advisory Committee "can affect millions of young girls like her"); Pl. Supp. Br. at 13 (arguing that ensuring the "public health and welfare of [U.S.] citizens" mandates granting her motion). There is no legally protected interest under the Constitution or common law for public access to discovery materials that are subject to a protective order, *unless* the materials have been *filed* and *relied upon* by the Court to determine the parties' substantive rights. *See Seattle Times*, 467 U.S. at 33; *Mokhiber v. Davis*, 537 A.2d 1100, 1109 (D.C. Ct. App. 1998); *Simon v. G.D. Searle & Co.*, 119 F.R.D. 683, 684 (D. Minn. 1987) (Renner, J.). The Seventh Circuit has made clear that, though the public has a presumptive right to access discovery materials filed with the court, "the same is not true of materials produced during discovery but *not* filed with the Court," *Bond v. Urteras*, 585 F.3d 1061, 1073 (7th Cir. 2009) (emphasis added); *see also Johnson v. Allstate Ins. Co.*, No. 07-0781, 2008 WL 4279992, at *1 (S.D. Ill. Sept. 17, 2008) (Reagan, J.) (recognizing

[7] *See Avis Rent A Car System, Inc. v. Aguilar*, 529 U.S. 1138 (2000) (dissent to Supreme Court's denial of certiorari for case involving injunction against harassing speech in workplace); *Near v. Minnesota*, 283 U.S. 697 (1931) (injunction prohibiting the publication of expressive material found to be a prior restraint); *Chicago Council of Lawyers v. Bauer*, 522 F.2d 242, 248-49 (7th Cir. 1975) (local criminal rule of district court seeking to proscribe extrajudicial comments by attorneys did not constitute prior restraint); *Alexander v. U.S.*, 509 U.S. 544, 549-50 (1993) (court-ordered forfeiture of assets used in furtherance of racketeering activities did not constitute prior restraint); *Procter & Gamble Co. v. Bankers Trust Co.*, 78 F.3d 219, 225 (6th Cir. 1996) (permanent injunction prohibiting publication of news story constituted prior restraint).

that "the Seventh Circuit has specifically noted that '[s]ecrecy is fine at the discovery stage, before the material enters the judicial record'") (*quoting Baxter Int'l, Inc. v. Abbott Labs.*, 297 F.3d 544, 545 (7th Cir. 2002)). Here, the challenged documents have not been filed or relied upon by the Court, and therefore there is no Constitutional or common law basis to allow the PSC to disseminate confidential information it obtained through pretrial discovery.

**B. Principles of Comity Require that the Challenged Documents Remain Confidential.**

The PSC also argues that plaintiff's First Amendment claim deserves special consideration because one of the bases for the confidentiality of Bayer's documents arises out of foreign law. *See generally* Pl. Supp. Br. As a preliminary matter, as demonstrated above, plaintiff has no First Amendment right to disseminate Bayer's confidential documents received through pretrial discovery. *Supra* Part I(A). Thus, there is no conflict with foreign law.

Even if a conflict between foreign and U.S. law existed—and it does not—the PSC misconstrues the balancing of interests that a court should consider. When foreign law prohibits disclosure of information, a reviewing court must conduct "a sensitive balancing of the competing interests at stake," taking into account the concept of international comity. *United States v. First Nat'l Bank of Chicago*, 699 F.2d 341, 345 (7th Cir. 1983). The Supreme Court has made clear that principles of comity require U.S. courts to tread lightly where American and foreign law may potentially conflict:

> American courts, in supervising pretrial proceedings, should exercise special vigilance to protect foreign litigants from the danger that unnecessary, or unduly burdensome, discovery may place them in a disadvantageous position. Judicial supervision of discovery should always seek to minimize its costs and inconvenience and to prevent improper uses of discovery requests. When it is necessary to seek evidence abroad, however, the district court must supervise pretrial proceedings particularly closely to prevent discovery abuses. . . . Objections to "abusive" discovery that foreign litigants advance should therefore receive the most careful consideration.

*Societe Nationale Industrielle Aerospatiale v. U.S. Dist. Ct. for the So. Dist. of Iowa*, 482 U.S. 522, 546 (1987). *See also Gerling Global Reinsurance Corp. v. Quackenbush*, No. S-00-0506WBSJFM, 2000 WL 777978, at *10 (E.D. Cal. June 9, 2000) (Shubb, J.) (preliminarily enjoining enforcement of state law requiring insurance companies to disclose information about policies issued in Europe because conflict with the BDSG might interfere with the federal government's control over foreign affairs). "American courts have developed certain rules of self-restraint governing the appropriate exercise of their power" in these circumstances. *Dexia Credit Local v. Rogan*, 231 F.R.D. 538, 542 (N.D. Ill. 2004) (Schenkier, M.J.).

In light of these comity considerations, U.S. courts have held that German defendants should not be subject to discovery that would force them to violate German privacy laws. In *Volkswagen, AG v. Valdez*, 909 S.W.2d 900, 902-3 (Tex. 1995) (per curiam), the Texas Supreme Court reversed without argument a discovery ruling that would have required the defendant to produce materials in violation of German privacy law. S*ee also In re Baycol Prods. Liab. Litig*., MDL No. 1431, 2003 WL 22023449, at *6 (D. Minn. Mar. 21, 2003) (Lebedoff, M.J.) (finding that "Germany's interest in protecting the privacy of [employee performance evaluations] outweighs the Plaintiffs' claimed interests in this litigation"); *In re Vitamins Antitrust Litig.,* No. 99–197TFH, 2001 WL 1049433, at *9 (D.D.C. June 20, 2001) (Hogan, J.) (requiring plaintiffs to determine whether materials protected as private under German law were "absolutely essential" to their case and, if so, whether the protective order could be amended to "safeguard defendants from liability in the production of this information").

That is why the PSC conceded, by stipulating to entry of the Protective Order, that the BDSG is a valid basis for designation of materials as confidential in this litigation, thereby enabling Bayer Pharma AG to lawfully produce over 22 million pages of documents. CMO 7

(D.E. 291 in MDL 09-2100) at § II.B. Moreover, this Court already has ruled, by entering the Protective Order and denying plaintiffs' motion to de-designate the EURAS Case Summaries, that German privacy laws are applicable to documents produced by Bayer Pharma AG through discovery in this litigation. *See* D.E. 1971 in MDL 09-2100; *see also supra* n. 4.

The PSC nevertheless argues that, because plaintiff has raised a First Amendment challenge, her interests must outweigh any interest advanced by foreign law. Pl. Supp. Br. at 11-16. But if merely raising the specter of the First Amendment were sufficient to "outweigh" foreign law, principles of comity would cease to exist, protective orders (including those agreed to the parties prior to production in discovery) would become meaningless, and discovery involving foreign companies subject to more restrictive privacy laws would become more complex and burdensome, at the very least, and possibly unlawful. Here, the PSC has not identified a single case that rejected foreign law to permit *dissemination* of materials received in pretrial discovery.[8] Even those cases identified by the PSC that concern discovery materials ordered their *production*, not *dissemination*. *Guccie America*, 2010 WL 808936, at *7; *Hagenbuch*, 2005 WL 6246195, at *6; *Great Lakes* 1990 WL 147066, at *3; *In re Automotive*

[8] *See* Pl. Supp. Br. at 11-13 (citing *U.S. v. Vecto, Inc*., 691 F.2d 1281, 1287 (9th Cir. 1981) (addressing enforcement of summonses issued by the Internal Revenue Service); *Gucci America, Inc. v. Curveal Fashion*, No. 09 Civ. 8458(RJS)(THK), 2010 WL 808639, at *7 (S.D.N.Y. Mar. 8, 2010) (Katz, M.J.) (requiring production of documents responsive to subpoena); *Hagenbuch v. 3B6 Sistemi Elettronici*, No. 04 C 3109, 2005 WL 6246195, at *6 (N.D. Ill. Sept. 12, 2005) (Ashman, M.J.) (requiring response to discovery requests); *Great Lakes Dredge & Dock Co. v. Harnischfeger Corp*., No. 89 C 1971, 1990 WL 147066, at *3 (N.D. Ill. Sept. 25, 1990) (Guzman, M.J.) (requiring party to produce individuals for deposition and to respond to interrogatories and document requests); *In re Automotive Refinishing Paint Antitrust Litig*., 358 F.3d 288, 305 (3d Cir. 2004) (permitting plaintiffs to seek jurisdictional discovery under the Federal Rules of Civil Procedure)).

*Refinishing Paint*, 358 F.3d at 305. Bayer Pharma AG, of course, has already produced the challenged documents.[9]

In this instance, where the documents at issue have already been produced, comity principles weigh heavily in favor of maintaining the confidentiality designations. The confidentiality designations have no effect on the PSC's ability to use the information so designated in the course of this litigation. CMO 7 (D.E. 291 in MDL 09-2100) at § II.E. Principles of comity would have little meaning—and voluntary production of documents would come to a screeching halt—if a plaintiff was permitted to disseminate information otherwise protected from disclosure simply by declaring her First Amendment right to do so.

**********

In sum, the First Amendment does not entitle plaintiff to disseminate confidential materials obtained through pretrial discovery. The Court, therefore, for the reasons set forth below, need only find that the confidential documents are appropriately designated under Fed R. Civ. P. 26(c).

## II. NEARLY ALL OF THE DOCUMENTS PRODUCED BY BAYER PHARMA AG MUST REMAIN CONFIDENTIAL PURSUANT TO GERMAN PRIVACY LAW.

Twenty-eight of the thirty documents produced by Bayer Pharma AG were properly designated as confidential pursuant to CMO 7 § II.B, which provides that German entities may designate as confidential discovery material "containing 'personal data' within the meaning of the German Federal Data Protection Act, the confidentiality of which is protected under German

[9] The PSC devotes numerous pages of its supplemental brief discussing Bayer Pharma AG's ties to the United States in an apparent effort to demonstrate that it may be subject to U.S. laws and discovery obligations. Pl. Supp Br. 1-3, 14-16. The PSC's argument is irrelevant. Bayer Pharma AG already produced the confidential documents that plaintiff now seeks to disseminate. Moreover, Bayer Pharma AG's ties to the United States, which the PSC mischaracterizes in any event, do not subject it to obligations beyond those mandated by U.S. law and does not relieve Bayer Pharma AG of its obligations under German law.

law."[10] CMO 7 (D.E. 291 in MDL 09-2100) at § II.B. The two remaining documents are confidential for other reasons, as set forth in Part III.

**A. Application of the German Federal Data Protection Act ("BDSG").**

***Basic principles of the BDSG.*** Under German law, "data protection is recognized as a fundamental right and high-ranking legal principle." Declaration of Dr. Henning Moelle (Nov. 7, 2011) ("Moelle Decl.") (Ex. B) ¶ 8. The scope of the constitutional right "of every individual to determine the use of data that concern his or her person"—including "which personal data may be collected or used by whom for which purpose and under which conditions"—is codified in the BDSG. *Id.* ¶¶ 8-9. "As federal law, it applies in all German states…[and] also applies to the" documents at issue here. *Id.* ¶ 14. Violations of the BDSG are subject to prosecution as administrative or criminal offences and are punishable by fines, injunctive relief, restitution, and imprisonment of up to two years. *Id.* ¶ 12. Moreover, data protection enforcement agencies have the authority to shut down the business operations of companies found to be in violation of the BDSG. *Id.*

The BDSG presumptively prohibits the "collection, processing and use of personal data" in order "to achieve a maximum degree of data protection." Moelle Decl. ¶ 11. Processing of data within the sense of the BDSG includes "any transfer of data." *Id.* ¶ 25, n. 2 (referencing BDSG § 3(4)). "[P]ersonal data" is broadly defined to encompass "any information concerning the personal or material circumstances of an identified or identifiable individual." *Id.* ¶ 13 (emphasis omitted) (quoting BDSG § 3(1)). The BDSG applies to personal data processed in Germany regardless of the nationality, citizenship, or domicile of the individual to whom the information pertains. *Id.* ¶ 8.

[10] *See* Bayer Addendum Items 16-24; 26-29; 32-43; 56-58.

***The BDSG is controlling because it is not superseded by a more rigid data protection law.*** The PSC cites an article by an American scholar, Robert G. Schwartz, Jr., to suggest that "whether the Act actually covers the requested documents is particularly suspect in light of the fact that the [BDSG] may not control in many jurisdictions in Germany and the scope of its influence has been questioned." Pl. Supp. Br. at 10; *see also id*. at n. 26 ("'[s]tate laws have largely replaced the [BDSG]' and 'by its own provisions [the BDSG] is only binding if other legislation does not regulate the particular data processor'") (quoting Schwartz). As Dr. Moelle points out, the PSC appears "to have been misguided by an incorrect and incomplete reading of the" Schwartz publication. Moelle Decl. ¶ 14. First, the Schwartz article was published in 1992, and therefore "does not account for the enactment of the EU Data Protection Directive of 1995 or for various other amendments which have been made to the BDSG to reinforce the protection of personal data since then." *Id*. Second, the PSC misconstrues the Schwartz article and takes statements from that article out of context. *Id*. Importantly, Schwartz acknowledges that ***the BDSG is superseded only to the extent that the data processor is subject to other data protection laws which establish an even more rigid level of data protection*** in specific sectors. *Id*. In other words, the BDSG represents the floor for data protection in Germany, not the ceiling. Because no "sector-specific" data protection law establishing "an even more rigid level" of protection applies here, the BDSG governs. *Id*.

***Bayer Pharma AG is subject to the BDSG despite the fact that Yasmin/YAZ are marketed in the United States.*** The PSC also wrongly suggests that the documents at issue need not be maintained as confidential because Bayer Pharma AG has ties with Bayer entities in the U.S. and has allegedly "subjected" itself "to American regulations, in particular the" FDCA. Pl. Supp. Br. at 4; *see generally id*. at 1-5. However, because Bayer Pharma AG, a German

company, has collected, processed, and transferred the documents at plaintiffs' request for purposes of this litigation, it is the "controller of the personal data," "bound by the BDSG and exposed to sanctions in case of any violation of the BDSG." Moelle Decl. ¶ 15. As Dr. Moelle notes:

> Bayer AG faced a similar issue in 2003 when the New York Times challenged the confidentiality of documents produced in connection with the Baycol litigation. Like Bayer Pharma AG, Bayer AG was affiliated with companies in the U.S. which were responsible for marketing the medication at issue in the U.S. Nevertheless, Bayer AG received a letter from Dr. Heger, Head of the Department of International Law of Civil Procedure, Mutual Judicial Assistance and Arbitration at Germany's Federal Ministry of Justice, making clear that vacating the protective order would create a state of affairs incompatible with the right of informational self-determination guaranteed by the BDSG and the German Constitution. Dr. Heger went on to state that ***publication of protected data would prevent Bayer AG from producing additional personal data in US proceedings***.

*Id*. ¶ 16 (emphasis added) (attaching Certified English translation of Letter from German Ministry of Justice as Exhibit C to his declaration). Contrary to the PSC's suggestion, then, maintaining the confidentiality of documents subject to protection under the BDSG is not only necessary, but failure to do so may prohibit Bayer Pharma AG from producing additional personal data in connection with U.S. litigation.

### B. Twenty-Eight of the Documents Produced by Bayer Pharma AG Must Be Maintained as Confidential Under the BDSG.

Dr. Moelle has reviewed the documents in question and has concluded that twenty-eight of the documents produced by Bayer Pharma AG fall squarely within the definition of personal data set forth in the Protective Order and in the BDSG, because they "include names, job titles, phone numbers, email addresses, or other personal data for literally hundreds of individuals, and thus concern the "personal or material circumstances of an identified or identifiable individual." Moelle Decl. ¶ 19; *see also* CMO 7 (D.E. 291 in MDL 09-2100) at § II.B ("'Personal data' consists of any and all data that concerns an identified person or a person who is identifiable with

recourse to additional information available to the data processor").[11] As a general matter, the BDSG prohibits a transfer of personal data to any jurisdiction that "does not provide for rules on data protection functionally equivalent to the EU and therefore does not provide for 'an adequate level of data protection.'" Moelle Decl. ¶ 21 (emphasis omitted). German and EU lawmakers have determined that U.S. data privacy laws do not provide for an adequate level of data protection. *Id*.

As an exception to the rule, "the BDSG allows the transfer of personal data outside the European Union and the EEA to the extent that the transfer is necessary 'for the establishment, exercise or defence of legal claims.'" *Id*. ¶ 22 (citing BDSG § 4c(1)(4)) (emphasis omitted). The PSC argues that this exception (or "derogation") is the end of the discussion and "may allow for the transfer of Bayer's documents." Pl. Supp. Br. at 10 (discussing BDSG § 4c(1)(4) and *Accessdata Corp. V. Alste Technologies GMBH*, No. 2:08-cv-569, 2010 WL 318477 (D. Utah Jan. 21, 2010)). The PSC, however, has misinterpreted this provision of the BDSG, as it "does not derogate the *general* BDSG requirements for the processing and transfer of personal data." Moelle Decl. ¶ 23. Instead, Bayer Pharma AG may "only lawfully transfer, process and use the documents [1] with the data subject's consent or [2] if other provisions of the BDSG permit such transfer, processing and use." *Id*. ¶ 24. Application of these principles establishes that the documents at issue must remain confidential under the BDSG.

***Consent of the data subjects is not a viable option.*** First, Bayer Pharma AG has produced over 22 million pages of documents in this litigation and those documents include personal data from many thousands of data subjects. Obtaining consent of all data subjects to make these documents available without the confidentiality afforded under the Protective Order,

[11] *See* Bayer Addendum Items 16-24; 26-29; 32-43; 56-58.

which generally must be given in writing, would be highly impractical and very likely impossible. Moelle Decl. ¶ 27. Even obtaining consent in connection with the twenty-eight documents at issue here would require Bayer to contact hundreds of employees, former employees, and individuals with no current or past employment relationship with Bayer. *Id*. Second, individual data subjects are unlikely to give their consent here, where the PSC's stated intention is to use the documents to assert that Bayer and its employees have somehow misled the FDA. Moelle Decl. ¶ 27. *See* Pl. Supp. Br. at 4 (stating that "[a] significant aspect of Plaintiff's claim is that the Bayer entities have not submitted the required safety information to the FDA"); Pl. Mot. at 3 (asserting that "the Bayer submissions to [the FDA] have misconstrued the available data….").[12] Consent must be "based on the data subject's free decision" (an employer may not require its employee to give such consent) and the employee must be free to withdraw his consent if he later changes his mind. Moelle Decl. ¶ 26.

***Other provisions of the BDSG permit transfer, but require Bayer Pharma AG to maintain the documents as confidential.*** Under the BDSG, Bayer may disclose personal data only if a statutory exception so allows. The only exception potentially applicable in these circumstances, because consent is not a viable option, allows for the processing of personal data "as far as necessary to safeguard legitimate interests of the controller [if] there is no reason to assume that the data subject has an overriding legitimate interest in ruling out the possibility of processing or use." Moelle Decl. ¶ 29 (quoting BDSG § 28(1)(2)). As discussed *supra* p. 17, disclosure in defense of a legal claim may constitute a legitimate interest in certain instances. *Id.* ¶¶ 31-32. The PSC's interest in petitioning the FDA "cannot constitute a genuine interest of

[12] Such a "claim," of course, would be precluded by the Supreme Court's decision in *Buckman* if raised in this litigation. *See Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350-51 (2001) (FDCA empowered FDA, not state courts or juries, to decide whether a fraud was committed on FDA).

Bayer (the data controller) as…required under [BDSG § 28(1)(2)]." *Id.* ¶ 32. To ascertain whether disclosure of personal data is permissible under the BDSG, Bayer Pharma AG must weigh the interest in the processing and transfer of the personal data for the purpose of the litigation against the constitutional rights of the data subjects, taking into account the principle of proportionality, the nature of the personal data, and the relevance of the personal data to the litigation. *See id.* ¶ 5.

In some circumstances, the imposition of confidentiality obligations upon the recipient of the data, such as those provided for in the Protective Order, can adequately mitigate the countervailing privacy interests of the data subjects. *Id.* ¶ 6. Such confidentiality provisions factor into the balancing test required under the BDSG. *Id*. Bayer Pharma AG's decision to produce the twenty-eight documents at issue and millions of pages of other documents, after application of the balancing test, hinged on its ability to maintain them as confidential pursuant to the Protective Order agreed to by the parties and entered by this Court. Dr. Moelle observes several factors which collectively suggest "Bayer would violate German data protection laws if it disclosed the documents at issue without protection by the confidentiality designation and the Protective Order," *id*. ¶ 33:

- "[T]he individuals to whom the documents relate are foreign to the US litigation and have no direct genuine interest in the disclosure of their personal data." *Id*. ¶ 34.
- "German courts as well as the German [legislature] have expressed the high importance which must be placed [on] the protection of an individual's personal data and to the need to strictly limit their use." *Id*. ¶ 36.
- "[I]f the twenty-eight documents were de-designated for petitioning the FDA, the data subjects would run the risk that any third party to which their personal data is disclosed or may otherwise become known in the course of the FDA hearing could later process, transfer or use their personal data for any other purpose without obeying the limits set by German data protection law." *Id*. ¶ 35.
- "If the documents were de-designated, there would no longer be a sufficiently effective safeguard in place to ensure that the personal data must not be used for any

> purpose other than the 'legitimate purpose' (namely the US litigation) for which they had originally been processed and transferred in accordance with the German Data Protection Act. Unless the Protective Order and the designation of the documents as confidential continues to prevent the documents from being used for purposes other than the US litigation, Bayer (or any other German company in a similar situation) would risk sanctions for violation of the BDSG." *Id*. ¶ 36.

Bayer was able to produce the twenty-eight documents at issue because those documents could be designated as confidential under the Protective Order, which balanced Bayer's interest in responding to discovery in this litigation with the data subjects' interest in maintaining the privacy of their personal data. *See id*. ¶ 37. *See In re Vitamins*, 2001 WL 1049433, at *9 (requiring plaintiffs to determine whether materials protected as private under German law were "absolutely essential" to their case and, if so, whether the protective order could be amended to "safeguard defendants from liability in the production of this information"); *Volkswagen*, 909 S.W.2d at 902-3 (reversing discovery ruling requiring defendant to produce materials in violation of German privacy law).

The confidentiality designation has no impact on the PSC's ability to use the documents at issue in the course of this litigation. "However, if the twenty-eight documents at issue were de-designated, the conditions for process and transfer would not be met. Bayer would risk violating German data protection laws if the documents were now de-designated as demanded by the plaintiffs. Bayer and its officers respectively would then risk prosecution under German data protection laws." Moelle Decl. ¶ 37.

## III. THE REMAINING DOCUMENTS ARE CONFIDENTIAL UNDER RULE 26 AND OTHER APPLICABLE LAW.

"FRCP 26(c)(1)(G) permits a court to, 'for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including…(G) requiring that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a specified way.'" *In re Northshore Univ. Healthsystem*, 254 F.R.D. 338, 341 (N.D. Ill. 2008) (Denlaw, M.J.) (citing Fed. R. Civ. P. 26(c)(1)(G)); *see also Star Scientific, Inc. v. Carter*, 204 F.R.D. 410, 413 (S.D. Ind. 2001) (Baker, Mag.) (finding that customer lists, information relating to consumer purchasing habits, pricing information, and sales techniques, sales volumes, and manufacturing techniques were documents deserving of confidentiality protection). The remaining documents are properly designated confidential because they reflect trade secrets and intellectual property.[13]

### A. Documents that Reveal Trade Secrets are Subject to Confidentiality Protection Under the Rules of Civil Procedure and 7th Circuit Precedent.

"Good cause may be established by showing that particular information amounts to a trade secret such that disclosure would put the holder at a competitive disadvantage if made public." *Jamsports & Entm't, LLC v. Paradama Prods.*, No. 02-2298, 2005 WL 14917, at *2 (N.D. Ill. Jan. 3, 2005) (Kennelly, J.) (designating various documents confidential and granting a protective order). Courts in the Southern District of Illinois have referred to the Illinois Trade Secrets Act and the Restatement of Torts to determine which documents are trade secrets and/or confidential information. *See Hal Wagner Studios, Inc. v. Elliott*, No. 09-0031, 2009 WL 854676, at *3-5 (S.D. Ill. Mar. 30, 2009) (Reagan, J.) (granting protective order over customer

[13] The remaining documents include 19 documents produced by Bayer HealthCare Pharmaceuticals Inc. and the two documents produced by Bayer Pharma AG that are not confidential under the BDSG. Seven additional documents produced by Bayer Pharma AG, confidential under the BDSG, are also confidential for other reasons.

lists, documents that explain pricing architecture, actual work product created for clients, and other information that was stored on computers). The Illinois Trade Secrets Act defines a trade secret as "information, including but not limited to, technical or non-technical data, a formula, pattern, compilation, program, device, method, technique, drawing, process, financial data, or list of actual or potential customers or suppliers, that: (1) is sufficiently secret to derive economic value, actual or potential, from not being generally known to other persons who can obtain economic value from its disclosure or use; and (2) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy or confidentiality." 765 ILCS 1065/2(d); *see also Johnson*, 2008 WL 4279992 at *1 (finding that pricing information was subject to a protective order because the party "regarded [the information] as proprietary and confidential, access to such documents [was] extremely limited, . . . few employees overall are given access to the information, . . . [and] spent millions of dollars in gathering the information and that the information has great commercial value").[14]

**1. Nonpublic Corporate Product Research.**

Twelve of the documents that the PSC wants to de-designate fall into the category of non-public research reports related to YAZ or other Bayer products. These documents consist of internal analyses and clinical study reports.[15]

Good cause exists to maintain the confidentiality designation for these non-public reports because they are trade secrets. *See Star Sci., Inc.*, 204 F.R.D. at 416 (finding that the potential

[14] Illinois District Courts have also used the following six factors from the Restatement of Torts: "(1) the extent to which the information is known outside the…business; (2) the extent to which it is known by employees and others involved in the…business; (3) the extent of measures taken by the [party] to guard the secrecy of the information; (4) the value of the information to the [party] and to the [party's] competitors; (5) the amount of effort or money expended by the [party] in developing the information; and (6) the ease or difficulty with which the information could be properly acquired or duplicated by others." *Id.*

[15] *See* Bayer Addendum Items 1-7, 9, 11, 13, 16, 25.

for a competitor to gain access "to information relating to how [a party] process[es] their product, *its research and development*, along with the terms and conditions of a contract with one of their customers, [] present potential dangers" and are therefore subject to confidentiality protection); *Elm Energy & Recycling v. Basic*, No. 96-1220, 1996 WL 596456, at *16 (N.D. Ill. Oct. 9, 1996) (Guzman, M.J.) (granting confidential designation and protective order over "trade secrets or confidential research [and] development or commercial information"); *Metavante Corp. v. Emigrant Sav. Bank*, No. 05-1221. 2008 WL 4722336 (E.D. Wis. Oct. 24, 2008) (Stadtmueller, J.) (finding that reports assessing the performance of a company's product were subject to a confidentiality designation and a protective order); *Containment Techs. Group, Inc. v. Am. Soc'y of Health Sys. Pharmacists*, No. 07-997, 2008 WL 4545310, at *1-2 (S.D. Ind. Oct. 10, 2008) (Baker, M.J.) (approving a "proposed protective order . . . for designation of confidentiality to research and development data" among other things because the party "spent significant amounts of money and countless hours of employee time…and [kept] certain information relating to its products and business **confidential** and secret because the disclosure of such information to competitors would be very damaging") (emphasis added).

Specifically, these twelve documents should be maintained as confidential trade secrets because they include technical and non-technical data and/or a compilation of data. *See* 765 ILCS 1065/2(d) (defining a trade secret as information, including . . . technical or non-technical data,…[and] compilation[s]). These reports contain highly sensitive information, which is of high value to Bayer because they are essential in the development of Yasmin/YAZ and other products. *See* Declaration of Sharon Brown (Nov. 9, 2011) ("Brown Decl.") (Ex. C) at ¶ 6-8; *see also Kimberly-Clark Corp. v. Tyco Healthcare Retail Group, Inc.*, No. 05-0985, 2006 WL 6652868, at *1-2 (E.D. Wis. Apr. 6, 2006) (Griesbach, J.) (approving protective order

designating "research and development information and plans for products not yet released to the marketplace" as "Highly Confidential Information").

If the information contained in these reports is made public, the highly competitive nature of the pharmaceutical industry would nearly guarantee that Bayer's competitors would use it to gain a competitive advantage over Bayer in the oral contraceptive market. *See* Brown Decl. ¶¶ 6-7, 10; Declaration of Dr. Bettina Fiedler (Nov. 9, 2011) ("Fiedler Decl.") (Ex. D) ¶¶ 6-7, 9. "Information concerning competitors' studies is of substantial value to other contraceptive manufacturers, because it can inform their own research and development, as well as their marketing efforts, and allow them to avoid some or all of the cost of developing their own plans." Brown Decl. ¶ 6. "Public disclosure of BPAG's proprietary research would unfairly make them an unwilling R&D arm of their competitors." Fiedler Decl. ¶ 7. Moreover, "public disclosure of past, ongoing and future research would allow any competitor to develop counter-strategies to downplay or offset the market effect of those studies." Brown Decl. ¶ 7.

Bayer has taken great lengths to protect the confidential data and information contained in these research reports through technical and contractual measures and a system of internal designation of information. *See* Brown Decl. ¶¶ 3-5; Fiedler Decl. ¶¶ 3-5. Specifically, Bayer employees are required upon employment to sign an agreement to maintain the confidentiality of business data, and physical access to Bayer's facilities is monitored and restricted. Brown Decl. ¶ 3. Additionally, Bayer has an extensive system in place to protect its electronic data. Brown Decl. ¶ 4. Finally, confidential data like research reports and regulatory information are stored with restrictions in place that limit access to only authorized employees. Brown Decl. ¶ 5.

Additionally, these reports would be considered trade secrets under the alternative analysis found in the Restatement of Torts. *See* Restatement of Torts § 757; *see also infra*. n.14.

First, none of these reports have been published and the reports are not disseminated outside of Bayer's business.[16] *See* Brown Decl. ¶8. To the extent that some of these reports have been given to the FDA,[17] the Dutch Medicine Evaluation Board,[18] or other authorities, these regulators have agreed to keep the reports confidential. *See, e.g.*, Bayer Addendum Items 3-6. Any employees or consultants who have access to this information are required to sign a confidentiality agreement and many of the documents have been designated with internal confidentiality restrictions thus limiting access to the documents. *See* Brown Decl. ¶5. As detailed previously, Bayer takes extensive steps to safeguard the information. *See* Brown Decl. ¶¶ 3-5; Fiedler Decl. ¶¶ 3-5. The information contained in these reports cost Bayer "hundreds of thousands, if not millions, of dollars" in order to develop each study and "thousands of man hours" of employee, researcher, and/or patient time to develop. Brown Decl. ¶ 6; *see also* Fiedler Decl. ¶ 6 ("[A] single clinical study can require thousands of man hours of work and depending on the size of the study hundreds of thousands, if not millions, of dollars in

[16] To the extent that the information in some of these reports has been published in some summary format, it has not been published with the level of detail contained in these reports and the detailed information contained in each report would be more useful and valuable to competitors than the publicized summaries. Brown Decl. ¶ 9.

[17] It should be noted that the FDA has agreed to keep many of these documents confidential because of a recognition on the part of the FDA that these documents are legitimate trade secrets. *See* Brown Decl. ¶ 9 ("[T]he FDA treats such information as being confidential and proprietary"). Courts in the Seventh Circuit have strongly considered the FDA's confidentiality designation for certain information when determining whether documents should be considered confidential as part of discovery. *See, e.g., In re Eli Lilly & Co.*, 142 F.R.D. 454, 459 (S.D. Ind. 1992) (Dillin, J.) (granting protective order allowing redaction of names from adverse event reports). Additionally, in as much as six of these documents are already in possession of the FDA and/or the Advisory Committee, but are subject to a confidentiality designation, plaintiff's argument that they are necessary to inform the FDA is inapposite. *See* Brown Decl. ¶ 9.

[18] Similarly, the Dutch equivalent of the FDA, the Medicine Evaluations Board ("MEB") agrees to keep these types of submissions and communications with the MEB confidential. *See* Fiedler Decl. ¶¶ 8, 10; *see also* Bayer Addendum Items 19-21, 28. Notably, "the MEB expects to be consulted and give permission before such materials are disclosed…and BPAG has no right to publicly disclose these documents itself. Fiedler Decl. ¶ 10.

expenditures to plan, implement, analyze and report"). Moreover, the information contained in each report would be extremely valuable to competitors who would want to develop similar products or find ways to compete with Bayer's products. *See* Brown Decl. ¶¶ 6-7, 10; Fiedler Decl. ¶¶ 6-7, 9.

**2. Marketing Related Materials.**

Fifteen of the documents that the PSC seeks to de-designate fall into the general category of marketing materials. These documents consist of "observations and guidance from external healthcare providers," discussions of "healthcare providers who are leaders in their respective fields," "minutes of the Global Brand Team discussing marketing strategy and planning," "discussions of factors relating to marketing development and growth," and "a report on trends in the development and marketing of oral contraceptives."[19] Brown Decl. ¶ 12; Fiedler Decl. ¶ 11. Key opinion leader/key customer lists are clearly trade secrets subject to confidentiality protection. *See United States ex rel. Liotine v. CDW-Government, Inc.*, No. 05-33, 2011 WL 718820 at *2 (S.D. Ill. Feb. 23, 2011). Additionally, non-public marketing related documents are also subject to protection. *See Kimberly-Clark Corp.*, 2006 WL 6652868 at *1-2.

The Seventh Circuit has found that customer lists and customer information are trade secrets. *See Am. Family Mut. Ins. Co. v. Roth*, 485 F.3d 930, 933 (7th Cir. 2007) (finding that information in a customer database were trade secrets under Wisconsin law because the information "represent[ed] an investment on the part of the firm seeking to protect it"). Moreover, Magistrate Judge Wilkerson of the Southern District of Illinois has specifically found that "customer lists or similar customer information that are not publicly available" are confidential information, which are subject to protection in a protective order. *Liotine*, 2011 WL

[19] Bayer Addendum Items 15, 17, 30, 33, 36, 42-43, 45-47, 49-51, 53, 56; *see* Brown Decl. ¶ 12; Fiedler Decl. ¶ 11.

718820, at *2 Additionally, courts have found that marketing materials are confidential information, which are properly subject to a protective order. *See, e.g.*, *Kimberly-Clark Corp.*, 2006 WL 6652868, at *1-2 (approving protective order that designated "currently implemented or not yet implemented marketing plans" as "Highly Confidential Information"); *PepsiCo, Inc. v. Redmond*, No. 94-6838, 1995 U.S. Dist. LEXIS 19437, at *39-40 (N.D. Ill. Jan. 26, 1995) (Lindberg, J) (finding that marketing materials were trade secrets), *aff'd* 54 F.3d 1262, 1271 (7th Cir. Ill. 1995); *see also MJ & Partners Rest. Ltd Partnership v. Zadikoff*, 10 F. Supp. 2d 922, 933 (N.D. Ill. 1998) (Moran, J.) (holding that "information regarding suppliers, sales, employee history, gross profits, revenues, expenses, financing agreements, investor lists, ***marketing plans,*** and special customer relationships" were properly alleged as **trade secrets**) (emphasis added).

Specifically, these seventeen documents consist of marketing materials that would be considered a trade secret under the Illinois Trade Secrets Act. The key opinion leader/key customer lists are akin to "list[s] of actual or potential customers or supplier[s]" as enumerated in the act. *See* 765 ILCS 1065/2(d). The other marketing materials are a "compilation" or "process" subject to protection under the act. *Id.* These marketing materials contain highly sensitive information, which is of high value to Bayer because the documents identify the key individuals that Bayer consults with and the information that these consultants have provided. *See* Brown Decl. ¶ 12. If these documents are made public, it is nearly certain that Bayer's competitors would use this information in connection with their own drugs. *Id*. Moreover, Bayer has gone to great lengths to protect the confidential data and information contained in these materials through technical and contractual measures and a system of internal designation of information. *See* Brown Decl. ¶¶ 3-5.

The materials also would be considered trade secrets under the Restatement of Torts. *See* Restatement of Torts § 757. Any employees or consultants who have access to this information are required to sign a confidentiality agreement and the information is maintained securely. *See* Brown Decl. ¶¶ 3-5; Fielder Decl. ¶¶ 3-5. The information contained in these documents would be extremely valuable to competitors who would want to use that information to market and or research their products. *See* Brown Decl. ¶12. Specifically, "[i]nformation concerning marketing and product development plans, and concerning persons who BHCP considers as leaders in the women's health medical community, who it may desire to use as consultants and, as reflected in some of the documents, that provides details of the consultations provided, would be valuable to competitors in their marketing of competing products." *Id.* For a competitor to develop similar marketing materials would require a similar investment of time, effort, and money.

**B. Documents that Reveal Intellectual Property are Subject to Confidentiality Protection Under the Rules of Civil Procedure and 7th Circuit Precedent.**

Three of the documents that plaintiff requests for de-designation are unpublished intellectual property of third parties, and therefore must be maintained as confidential.[20] The reports at issue represent extensive research and are the original works of the authors listed on each document. In many of the cases, the authors of the works have designated the document with some form of confidentiality stamp to prevent dissemination. For example, Addendum Item 11 contains the following statement on the front cover:

> **Confidential**. This document contains information and description of techniques that are proprietary to Ingenix i3 Drug Safety Epidemiology. It also contains information provided in confidence to Ingenix by Berlex Laboratories, Inc. This document is provided strictly for the use of Berlex Laboratories, Inc.

[20] Bayer Addendum Items 11, 13, 46.

The authors of this report consider it to be confidential intellectual property which they wished to prevent from being publicly disseminated.[21] "[T]hird parties demand and expect that BHCP will take steps to protect the confidential nature of their proprietary information." *See* Brown Decl. ¶ 11.

Courts in the Seventh Circuit have determined that intellectual property is a proper basis for a confidentiality designation. *See, e.g.*, *Sanimax AGS, Inc. v. Gulf Hydrocarbon, Inc.*, No. 09-37, 2010 WL 2560032, at *1-2 (S.D. Ind. June 23, 2010) (Baker, Mag.) (granting protective order designating a broad category of intellectual property as confidential information); *McManaway v. KBR, Inc.*, No. 08-186, 2009 WL 807641, at *1(S.D. Ind. Mar. 25, 2009) (Hussman, Jr., Mag.) (same); *see also PepsiCo, Inc. v. Redmond*, 1995 U.S. Dist. LEXIS 19437 at *37 (finding that one of the purposes of the Illinois Trade Secret Act was "[t]o safeguard intellectual property").

[21] As plaintiffs previously argued in resisting production of their experts' unpublished articles and data, authors consider it very important that their articles and research not be published without their consent because once publication occurs, the article and/or research is no longer capable of being published in a journal. *See, e.g., Common Statement on Prior Publication Policy by the Editors of Health Services and Health Policy Journals*, dated October 25, 2002, *available at* www.academyhealth.org/files/publications/policy.pdf ("The policy of the journals subscribing to this statement is to consider for publication only original work that has not previously been published . . . . It is the responsibility of authors to let editors know at the time of submission if a paper's contents have been previously disseminated in any manner so that the editors can determine whether to proceed with the review process."). As a result, it is important for this court to protect the future publication rights of these authors by preserving the current confidentiality designation. Specifically, Addendum Item 13 is an example of just such an unpublished report that is slated to be published in the near future.

Dated: November 9, 2011

Respectfully submitted,

*s/ John E. Galvin*

John E. Galvin (IL Bar #6205935)
Terry Lueckenhoff (Bar # 27810MO)
Fox Galvin, LLC
One S. Memorial Drive, 12th Floor
St. Louis, Missouri 63102
Telephone: (314) 588-7000
Facsimile: (314) 588-1965
jgalvin@foxgalvin.com
tlueckenhoff@foxgalvin.com

Adam L. Hoeflich (IL Bar # 6209163)
Brian S. Prestes (IL Bar # 6288528)
Bartlit Beck Herman Palenchar & Scott LLP
54 West Hubbard Street, Suite 300
Chicago, Illinois 60654
Telephone: (312) 494-4400
Facsimile: (312) 494-4440
adam.hoeflich@bartlit-beck.com
brian.prestes@bartlit-beck.com

Douglas R. Marvin
Williams & Connolly LLP
725 Twelfth Street N.W.
Washington, DC 20005
Telephone: (202) 434-5400
Facsimile: (202) 434-5029
dmarvin@wc.com

Susan A. Weber (IL Bar # 6211895)
Nathan A. Huey (IL Bar #6280257)
Sidley Austin LLP
One South Dearborn
Chicago, Illinois 60603
Telephone: (312) 853-7000
Facsimile: (312) 853-7036
saweber@sidley.com
nhuey@sidley.com

*Attorneys for Defendants Bayer HealthCare Pharmaceuticals Inc. and Bayer Pharma AG*

**CERTIFICATE OF SERVICE**

I hereby certify that on November 9, 2011, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all attorneys of record.

*s/ John E. Galvin*